11 June 2021
EMA/CHMP/287712/2021 Rev.1
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Final PROM[1] agenda for the meeting on June 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

14 June 2021, 09:00–16:00[2], virtual meeting / room 08-A

Disclaimers

Some of the information contained in this document is considered commercially confidential or sensitive and therefore not disclosed.

Of note, agendas and minutes are working documents primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

[1] The CHMP PReparatory and Organisational Matters (PROM) is a meeting to discuss CHMP organisational matters and other topics in preparation for the CHMP Plenary meeting. It is a virtual meeting, which usually takes place on Monday before the CHMP Plenary meeting. CHMP members, working party chairs and national experts together with EMA staff are participating in this forum. Depending on the nature of the issue and availability of documents and experts some PROM topics can be discussed at the CHMP Plenary.
[2] Note that the meeting may finish earlier depending on the length of the discussions.

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1. Agenda and Minutes

1.1. Welcome and declarations of interest of members, alternates and experts

1.2. Adoption of agenda

CHMP PROM agenda for 14 June 2021 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of June 2021 meeting will be adopted at the June 2021 CHMP plenary.

2. Non therapeutic-area-specific working parties

2.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

PCWP: Co-chair: Kaisa Immonen Co-chair: Juan Garcia Burgos (EMA)

HCPWP: Co-chair: Ulrich Jaeger Co-chair: Juan Garcia Burgos (EMA)

2.1.1. Agenda and minutes

- Draft agenda for PCWP-HCPWP Joint meeting held virtually on 01-02 June 2021
- Minutes from PCWP-HCPWP Joint meeting held virtually on 03-04 June 2021

Action: For information

2.2. Biologics Working Party (BWP)

Chairs: Sol Ruiz/Nanna Aaby Kruse

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by Adobe Connect on 12-14 April 2021
- Draft agenda for BWP meeting to be held by WebEx on 14-16 June 2021

Action: For information

2.2.2. Nomination of new alternate to the BWP

Nomination of new BWP alternate representing Italy.

Action: For endorsement

2.2.3. Revision of the Guideline on the requirements for quality documentation concerning biological investigational medicinal products (IMPs) in clinical trials - EMA/CHMP/BWP/534898/2008

Request from European Commission related to Clinical Trial Regulation. QWP working in parallel on the guideline for chemical IMPs (see 2.3.3).

Updates are proposed to the classification of changes to IMPs which require substantial modification of the IMPD (guideline chapter 6).

Draft guideline proposal to be published by CHMP in June for a targeted 2-month public consultation (i.e. chapter 6 only).

Action: For adoption

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Minutes

- Final minutes from QWP Core Team meeting held by teleconference on 12 May 2021
- Final minutes for QWP meeting held by Adobe Connect on 1-2 March 2021

Action: For information

2.3.2. Nomination of new Lithuanian member to the QWP

Nomination of new QWP member replacing Valdemaras Brusokas representing Lithuania.

Action: For endorsement

2.3.3. Revision of the Guideline on requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products (IMPs) in clinical trials - EMA/CHMP/QWP/545525/2017

Request from European Commission related to Clinical Trial Regulation. BWP working in parallel on the guideline for biological IMPs (see 2.2.2).

Updates are proposed to the classification of changes to IMPs which require substantial modification of the IMPD (guideline chapter 9).

Draft guideline proposal to be published by CHMP in June for a targeted 2-month public consultation (i.e. chapter 9 only).

Action: For adoption

2.4. Safety Working Party (SWP)

Chairs: Jan Willem Van der Laan/Susanne Brendler-Schwaab

2.4.1. Agenda and minutes

- Final minutes for SWP meeting held face-to-face/by teleconference on 19 April 2021

- Draft agenda for EMA/FDA non-clinical oncology cluster meeting to be held face-to-face/by teleconference on 8 June 2021

Action: For information

2.4.2. SWP response to CMDh request on the AI for N-nitrosovarenicline

The SWP has finalised a position on the acceptable intake of N-nitrosovarenicline, a nitrosamine impurity found to be present in some varenicline products. This position has been harmonised with international regulators in the nitrosamine international technical working group.

Action: For adoption

2.4.3. SWP response to CMDh request on 4-nitrosomorpholine (NMOR) in molsidomine

The SWP has finalised a position on the acceptable intake of N-nitrosomorpholine, a nitrosamine impurity known to be present in some molsidomine products.

Action: For adoption

2.4.4. Diethanolamine – SWP opinion for publication

SWP addressed CMDh questions on Diethanolamine and coconut oil diethanolamine condensate as excipients in 2018 and 2020. It is proposed to publish on EMA external website a position combining both opinions adopted by the CHMP in November 2018 and November 2020.

Action: For adoption

2.4.5. Change in nomination between Croatian SWP member and alternate

Nikolina Tori, current SWP alternate, to become member, and Jasenka Mrsic-Pelcic, current member, to become alternate.

Action: For endorsement

2.4.6. Call for nomination for the election of the SWP chair

Jan Willem van der Laan's second term will expire on 18 October 2021. Nominations have to be sent together with a CV and a brief motivation letter by 31 August 2021.

Action: For information

2.5. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

2.5.1. Agenda and minutes

- Agenda of BMWP meetings held virtually on 28 April 2021 and 26 May 2021
- Final minutes for BMWP meetings held on 31 March and 28 April 2021

Action: For information

2.6. Biostatistics Working Party (BSWP)

Chair: Kit Roes

2.6.1. Reflection paper on Statistical Issues in Quality Assessment - EMA/CHMP/138502/2017

Reflection paper on the topic of "Statistical Issues in Quality Assessment" and high-level overview of how the comments received were taken into consideration.

Chair: Kit Roes

Action: For adoption

2.7. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

2.7.1. Agenda

- Draft agenda of MSWP meeting held virtually via Webex on 02 June 2021

Action: For information

2.7.2. Nomination of new member to the Modelling and simulation Working Party

Nomination of new MSWP member representing France.

Action: For endorsement

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair (ad interim): Carolien Versantvoort

2.9.1. Questions from Committees, other Working Parties

- CMDh request for CHMP (PKWP) input regarding procedure Megestrol acetate 40 mg/ml oral suspension and bioequivalence study requirements for micronised suspension generic applications.
- PKWP (CHMP) response to CMDh request for input regarding procedure Tapentadol prolonged release capsules

Action: For adoption

2.9.2. PKWP Q&A on biowaivers for additional strengths of immediate release fixed combinations

Issue identified in a Scientific Advice procedure including request for information on how large can deviations from proportionality in composition be in the case of fixed combinations with highly soluble active substances in an application with multiple strengths. PKWP have developed a new proposed Q&A in response (complementing current existing PKWP Q&A 6.4).

Action: For adoption

2.9.3. PKWP request to CHMP to draft a Q & A on alternatives to rifampicin in drug-drug interaction (DDI) studies in healthy volunteers

CHMP previously adopted (CHMP plenary minutes April 2021) the Nitrosamine Implementation Oversight Group (NIOG) response (10 March 2021) to a question from PKWP on use of rifampicin in DDI studies in healthy volunteers. PKWP is now requesting agreement from CHMP to develop a Q&A for alternatives to rifampicin in such studies.

Action: For adoption

2.9.4. Change in composition to PKWP

Addition of a new expert.

Action: For adoption

2.9.5. Minutes

- Final minutes of PKWP meeting held via Webex on 19 May 2021

Action: For information

3. Therapeutic-area-specific working parties and SAGs

3.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

3.1.1. Agendas

- Final agenda of the annual EMA/PPTA-IPFA meeting held by teleconference on 10 June 2021
- Draft agenda for the Blood cluster meeting held by teleconference on 04 June 2021

Action: For information

3.2. Central Nervous System Working Party (CNSWP)

No topics

3.3. Cardiovascular Working Party (CVSWP)

No topics

3.4. Infectious Diseases Working Party (IDWP)

No topics

3.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

3.5.1. Agenda and minutes

- Final minutes for ONCWP meeting held by Adobe Connect on 06 May 2021
- Final agenda for ONCWP meeting held by Adobe Connect on 11 June 2021

Action: For information

3.6. Rheumatology/Immunology Working Party (RIWP)

No topics

3.7. Vaccines Working Party (VWP)

No topics

3.8. Scientific Advisory Groups (SAGs)

No topics

4. Drafting groups

4.1. Excipients Drafting Group

No topics

4.2. Gastroenterology Drafting Group (GDG)

No topics

4.3. Geriatric Expert Group (GEG)

No topics

4.4. Radiopharmaceuticals Drafting Group (RadDG)

No topics

4.5. Respiratory Drafting Group (RDG)

No topics

5. Harmonisation and consistency groups

5.1. International Council on Harmonisation (ICH)

5.1.1. Nomination of experts for ICH groups

- ICH Guideline Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
- ICH Guideline Q3E Guideline for Extractables and Leachables (E&L)

Action: For adoption

5.1.2. ICH E6 GCP principles

In the context of the ICH E6 (GCP) revision process, a new document – named draft "ICH E6 Principles" – has been published.

Action: For discussion

5.1.3. ICH S12 Biodistribution Studies for Gene Therapy Products

Step2b- New draft guidance ICH S12 Biodistribution Studies for Gene Therapy Products to be adopted for 4-month public consultation.

Action: For adoption

5.2. Guideline Consistency Group (GCG)

No topics

5.3. Summary of product characteristics Advisory Group

No topics

6. Joint groups and collaboration with other Scientific committees

6.1. Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of medicinal products (J 3RsWG)

No topics

6.2. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

No topics

6.3. Collaboration with other Scientific committees

6.3.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 07-10 June 2021

Action: For information

6.3.2. RMP safety specification assessment responsibilities for generic products – transfer from the CHMP to PRAC

Transfer of the safety specification assessment responsibilities for generic products from the CHMP to PRAC has been agreed in 2020, however due to COVID-19 BCP the transfer had not taken place. Proposal by EMA on a pragmatic way forward to enable the agreed transfer.

Action: For endorsement

7. Regulatory / Organisational matters

7.1. Regulatory Issues / new legislation

No topics

7.2. CHMP organisation / templates

7.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Appointment of CHMP peer review for SA

Action: For information

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 04 June 2021

Action: For adoption

8.2.2. ITF meeting

Meeting date: 30 June 2021

Action: For adoption

9. Product related topics

9.1.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

9.1.2. COVID-19 ongoing and upcoming procedures

List of currently ongoing and upcoming applications for COVID-19 vaccines and therapeutics.

Action: For information

9.1.3. Comirnaty – COVID-19 mRNA Vaccine (nucleoside modified) - EMEA/H/C/005735/X/0001

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst

Update on upcoming post-authorisation activities

Proposed procedure timetable

Action: For adoption

10. Any Other Business

10.1.1. Update from Research and Innovation workstream

The team will provide a summary of recent activities in the workstream's areas of Innovation Task Force, Horizon Scanning and Business Pipeline/Forecasting and is looking to open opportunities for Committee members to contribute to upcoming activities.

Action: For discussion

10.1.2. Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus Drafting Group

Proposal to establish a Drafting Group to revise the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus and call for nominations. Nominations to be sent by 12 July 2021.

Action: For endorsement

10.1.3. CHMP strategic, review and learning meeting under the Slovenian presidency of the Council of the European Union

Presentation on the SRLM under the Slovenian presidency for the 2nd part of 2021 to be introduced by SI CHMP member.

CHMP: Nevenka Tsinar

Action: For information

10.1.4. Future of presential plenary meetings

Discussion on the return to presential plenary meetings.

CHMP: Harald Enzmann

Action: For discussion

10.1.5. Lisboa criteria for comprehensiveness

Criteria to be added to the AR templates for assessor to consider during evaluation.

CHMP: Harald Enzmann

Action: For discussion